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***Deepali A Rao**, Head, Specialty Lines, India Insure Risk Management & Insurance Broking Services, talks about the benefits of insurance cover while conducting clinical trials*


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It has been close to a decade since India has been seeing the clinical trial industry grow. Global companies have been coming to India to conduct trials for their research drugs on a regular basis. India has been a preferred option for multiple reasons, population, cost effective and good quality resource availability, technologically on par with the global world and also the fact that we are a largely English speaking population. The industry has been growing steadily and is now getting closer to being a billion dollar industry in India alone. Like any other industry, this also has significant risks associated with it, especially considering that we are talking about experiments being done on human lives.

The growth in the industry has led to an increasing awareness amongst stakeholders about the severity of the risks associated and its possible financial impact on the organisations. This has led to the logical search for the right insurance cover which could protect their balance sheet. Initially clinical trial insurance was purchased by the local CROs only on the insistence of the international sponsor. Today, all key stakeholders in the chain are aware that conducting a clinical trial without an insurance cover in place would not be a wise and prudent business decision.

A quick overview of the value of insurance purchased by companies give an indication of the levels of compensation companies were offering or intending to offer to the volunteers. While internationally the indemnity limits are usually in the range of $2 million to $5 million, in India it was rare for companies to be looking at indemnity limits beyond ` 10 to 15 crores. It would be a rare case of a large company doing a very prominent trial where the indemnity limits would be much higher. Insurance companies have not seen too many claims on these policies and the ones see are not very large in no; thus indicating that the levels of compensation offered may not be a substantial amount. As a result the insurance industry has had a fairly profitable book of business from the clinical trial insurance covers; albeit a small book contributing to not more than one per cent of their total premium volumes.

A look at the insurance covers offered to the industry will reveal that the insurance products are definitely in line with what the international markets offer. The policies include coverage for not only the sponsor but all the stakeholders in the chain including the CRO, the ethics committee and the investigators as well. Policies tend to cover the 'No Fault Compensation', as well as the legal liability cover under the programme. The compensation conditions are typically defined within the policy and the amount of compensation is to be decided by an independent lawyer who would investigate the serious adverse event (SAE) and hear both parties, sponsors and the volunteers before arriving at the amount. So far sponsors and CROs have been satisfied with the insurance covers available.

Like any industry does, the clinical trials industry in India is also going through the regulatory evolution phase. From a time where there was little or no regulation about the compensations to be paid to volunteers in these trials, to a time today where the regulation is becoming so stringent that global

players are wanting to think twice before continuing their association in the country. The compensation guidelines which have come out earlier this year have the following critical aspects:

- The escalation matrix to be followed in case of an SAE
- The entitlements to a volunteer in case of a clinical trial related injury
- The methodology of arriving at the compensation payable
- The definition of a clinical trial related injury/ death

The compensation mechanism does appear to be very comprehensive and is very strongly in favour of the Research Subject (RS)/Volunteer who participate in the trials. The regulations insist on medical management to be provided to the RS for as long as required and also indicate that financial compensation should be paid to the RS or their nominee. If the sponsor were to trigger their insurance policy for both these aspects, they would need to first ensure that the value of insurance purchased is significantly higher than the current trends in the country. The insurance companies, however, would offer higher limits but would also insist on much higher deductible levels (self-insured portion of the risk) in order to avoid attritional losses. Many of the international underwriters who have been offering support to Indian companies on the clinical trial insurance policies have expressed their concern on these regulations and have indicated that they would not be very interested in continuing to offer support on these programmes.

The regulations also define cases which would be termed as clinical trials related injury/death. Product inefficacy has been termed as a clinical trial injury which is again raising a lot of eyebrows. The whole purpose of a clinical trial is to test the efficacy of a product. Insurance companies offer clinical trials insurance coverage on a 'No Fault Basis', however, it is a pre-requisite that there has to be an adverse event to the subject which could either be a drastic decline in the subject's condition which would not have been the case if regular medication had continued or a side effect leading to a completely new complication in the health of the subject. The insurance cover offered consequently is only to compensate a volunteer in case of any additional complications that may arise due to participation in a trial. All insurance policies very clearly exclude coverage for claims where the test drug/product fail to perform its intended purpose. This has been a practice not only in India but also internationally. Insurance companies are not contemplating deletion of this exclusion in light of the regulatory changes. This would have a direct impact on the sponsors/CROs and they would incur a higher financial burden. This could also lead to international sponsors not showing any more interest in the Indian Territory to conduct their clinical trials.

It is imperative to ensure the welfare of a volunteer; however, there is also an urgent need to safeguard the industry from collapsing all of a sudden. Keeping the regulations in line with international standards/jurisdictions would be prudent to make it a win-win situation to all. Without this, it is quite possible that the clinical trial industry in India would not grow at the pace it is growing, it may actually see a de-growth which would definitely not be healthy for the country itself.

Disclaimer: *The views expressed are that of the author and does not reflect the views of the companies. Insurance coverage mentioned above is only an interpretation and the actual coverage and exclusions would be as per the policies issued by various insurance companies.*

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